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10/662,552	09/15/2003	Xiaohui Zhang		2279

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EXAMINER	
SEREBOFF, NEAL	
ART UNIT	**PAPER NUMBER**
3626	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/19/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/662,552	ZHANG, XIAOHUI	
	Examiner	Art Unit	
	Neal R. Sereboff	3626	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 January 2004* is/are: a)☒ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1 – 15 are pending.

2. An examination of this application reveals that applicant is unfamiliar with patent prosecution procedure. While an inventor may prosecute the application, lack of skill in this field usually acts as a liability in affording the maximum protection for the invention disclosed. Applicant is advised to secure the services of a registered patent attorney or agent to prosecute the application, since the value of a patent is largely dependent upon skilled preparation and prosecution. The Office cannot aid in selecting an attorney or agent.

A listing of registered patent attorneys and agents is available on the USPTO Internet web site http://www.uspto.gov in the Site Index under "Attorney and Agent Roster." Applicants may also obtain a list of registered patent attorneys and agents located in their area by writing to the Mail Stop OED, Director of the U. S. Patent and Trademark Office, PO Box 1450, Alexandria, VA 22313-1450.

Claim Objections

3. Claims 6 and 9 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should be in the alternative. See MPEP § 608.01(n). Accordingly, claim 6 and claim 9 have not been further treated on their merits.

4. Claim 8 is objected to because of the following informalities: Claim 8 uses the phrase "said set of state variables" that describes the singular "set." "Are" is the plural conjugation of the verb is and so "said set of state variables are" implies that there is more than one set. The examiner is interpreting the verb as the singular is. Appropriate correction is required.

5. Claim 11 is objected to because of the following informalities: Claim 11 depends upon claim 10 and therefore includes all the limitations of claim 10. It is not necessary to repeat the language of claim 10 within claim 11. Appropriate correction is required.

6. Claim 15 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 15 includes a reference to claim 12 but claim 15 is dependent upon claim 1 not claim 12.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 1 – 15 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

9. The result of the instant invention is one or more numbers, generated by a human being. The numbers generated by the individual might be considered "useful" in the sense that the numbers may be used to determine epidemics. However, §101 requires that the results be reproducible. In the instant case, the model describing the categorized public health status is the result of subjective feelings about rule system components. Even that same person might generate different results at different times for the same conditions, as when the person might feel differently about the conditions at a later time. Moreover, since the result is subjective and dependent on a cognitive process, a person can be dishonest about how the person actually thinks a condition should be weighted, and generate any number within a given rule system. The

subjective component of the invention is not amenable to reproducibility of a result. In any event, the result is not concrete or tangible, but merely one or more numbers that may serve as input data for processing and use in a system not claimed.

10. Claim 1 recites no particular implementation of the idea of a rule system. The claim may require no more than presenting a number, reviewing the number, and an individual ruling upon the image mentally, or orally, or recording the rule result on a piece of paper, or having the rule result entered into a machine (not claimed) in a further process step (not claimed). The instant claims represent a disembodied "abstract idea." All of the claims are thus drawn to the abstract idea of a rule system, rather than to a practical application of the idea as required by 35 U.S.C. §101.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 1 – 15 are rejected under 35 U.S.C. 112, first paragraph, because the best mode contemplated by the inventor has not been disclosed. Evidence of concealment of the best mode is based first upon the Background of the Invention describing how the inventor's invention overcomes existing problems. Second, evidence of concealment is further shown in that one of ordinary skill in the art could not perform this invention because of the absence of both a method of practicing the invention within the written description and also the lack of a working example within the written description.

13. Claims 1 – 15 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure that is not enabling. A computerized system is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229; 188 USPQ 356 (CCPA 1976). As described, the application does not provide any structural implementation of the algorithm.

14. Claims 1 – 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The broad breadth of the claims and lack of detail within the written description provides no instructions on practicing this invention. The disease control nature of the invention requires that proper practice of the invention is necessary. Although the prior art is developed, the inventor states within the background that his invention overcomes missing systems. One of ordinary skill in the art requires a high amount of mathematical knowledge as evidenced by both the written description and also Goldenberg et al., "Early statistical detection of anthrax outbreaks by tracking over-the-counter medication sales" (see reference U on the attached PTO-892). The well developed prior art is explicitly differentiated by the inventor however the written descriptions provides no direction or assistance through either working examples or instructions. This lack of details makes a large amount of experimentation necessary. Therefore, one of ordinary skill in the art at the time the invention was made would not be enabled to make or use this invention.

15. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

16. Claims 1 – 15 ejected as failing to define the invention in the manner required by 35 U.S.C. 112, second paragraph.

17. The claim(s) are narrative in form and replete with indefinite and functional or operational language. The structure which goes to make up the device must be clearly and positively specified. The structure must be organized and correlated in such a manner as to present a complete operative device. The claim(s) must be in one sentence form only. Note the format of the claims in the patent(s) cited.

18. Claim 1 recites the limitation "rule system" in lines 23, 25, 30, and 33. There is insufficient antecedent basis for this limitation in the claim. The examiner notes that the definite article "the" is used to refer back to a previous object occurrence while the indefinite articles "a" or "an" are used to for the initial object occurrence.

19. Claim 1 recites the limitation "the state transition, the input sets, the output sets" in lines 22 – 23. There is insufficient antecedent basis for these limitations in the claim.

20. Claims 2 – 15 recite the limitation "apparatus" in the respective claims preambles. There is insufficient antecedent basis for this limitation in the claim.

21. Claim 3 recites the limitation "base line" in line 3. There is insufficient antecedent basis for this limitation in the claim. Claim 2 defines a "base line" and so claim 3 has been interpreted to be dependent upon claim 2.

22. Claims 3 – 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 3 – 5 use the mathematical term deviation without referring to where the

deviation is from. Claim 2 defines the average daily sales and claims 3 – 5 have been interpreted to deviate from the average daily sales and are therefore assumed to be dependent upon claim 2.

23. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 10 states that "it is mapped" but the object of what is being mapped is not defined.

Claim Rejections - 35 USC § 102

24. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

25. **Claims 1 – 5, 7, 10 – 15** are rejected under 35 U.S.C. 102(b) as being anticipated by Goldenberg et al., "Early statistical detection of anthrax outbreaks by tracking over-the-counter medication sales" (see reference U on the attached PTO-892).

26. As per claim 1, Goldenberg teaches the system for detecting an unusual public health status and for modeling the change of categorized public health status from over-the-counter (OTC) pharmaceutical sales data, comprising:

- A measurement scheme defined by a set of variables and calculations of categorized daily OTC sales data in a specified geographical scale (see page 2, Tracking Grocery Data section, paragraph 1 where geographical scale is noted by address)

- An algorithm for unusual public health status (or event) detection incorporating seasonally varying reference lines (see page 2, Tracking Grocery Data section, paragraph 5), and calculating three structural components from the input data:
    - A daily deviation from the reference line, (see Figure 3)
    - An n-days-cumulated-deviation, and (see Figure 3)
    - The change of the daily deviations in that area, (see Figure 3)
- A dynamic system model describing the categorized public health status by a set of state variables, and the change of the health status by the state transition, the input sets, the output sets, and the rule systems that govern them (see page 3, paragraph 1),
- The rule system determines the state transitions for modeling the dynamic change of public health status through the analysis of information derived from OTC pharmaceutical sales in that area (see page 3, paragraph 1),
- A rule system combines the structural components incorporating the confidence supporting sets as the input variables (see page 3, paragraph 2 where the confidence arises by defining the input boundaries),
- A rule system maps the state history to the output variables (see figure 5 where state history is determined by the amount of antibiotic being purchased).

27. As per claim 2, Goldenberg teaches the system of claim 1 as described above. Goldenberg further teaches the system wherein said measurement scheme includes the calculation of monthly (or weekly, or daily, or seasonally) averaged daily sales for the categorized OTC medicines as the base line, from the data in the past at the same place, which is one data set (base line) for supporting the rule system (see figure 1).

28. As per claim 3, Goldenberg teaches the system of claim 2, as understood, as described above. Goldenberg further teaches the system wherein said measurement scheme includes the calculation of the deviation of daily sales in the current-month from the base line, and it is measured in change of percentage at the same place, which is another data set (the first structural component) for supporting the rule system (see figure 3).

29. As per claim 4, Goldenberg teaches the system of claim 2, as understood, as described above. Goldenberg further teaches the system wherein said measurement scheme includes the calculation of the n-days-cumulated-deviation, which is another data set (the second structural component) for supporting the rule system (see figure 3).

30. As per claim 5, Goldenberg teaches the system of claim 2, as understood, as described above. Goldenberg further teaches the system wherein said measurement scheme includes the calculation of the daily change of the deviation, which is another data set (the third structural component) for supporting the rule system (see figure 3).

31. As per claim 7, Goldenberg teaches the system of claim 1 as described above. Goldenberg further teaches the system wherein said dynamic model of the categorized public health status is defined by the system with a set of state variables and state transitions over the time dimension at a specified place, with which state transitions model the change of the categorized public health status (see page 2, Tracking Grocery Data section, paragraph 1 where the state variables and public health are tracked through antibiotic sales).

32. As per claim 10, Goldenberg teaches the system of claim 1 as described above. Goldenberg further teaches the system wherein said input sets are the supporting sets for the state transition rule systems (see page 1 paragraph 3); it is mapped from the structural components

incorporating the confidence levels (see figure 2 and page 3 paragraph 2 where statistical quality control creates confidence levels).

33. As per claim 11, Goldenberg teaches the system of claim 10 as described above. Goldenberg further teaches the system wherein said input sets are the supporting sets for the state transition rule systems (see page 1 paragraph 3); it is mapped from the structural components incorporating the confidence levels (see figure 3 and page 3 paragraph 2 where statistical quality control creates confidence levels), where the confidence levels are derived from the historical data sets (see page 3 paragraph 2 where the historical data sets are the natural variation), and the confidence supporting sets are found from the cumulated distribution functions with the specified confidence levels (see figure 3 and page 3 paragraph 2 where the specified confidence level is the security band).

34. As per claim 12, Goldenberg teaches the system of claim 1 as described above. Goldenberg further teaches the system wherein said output sets are a set of vectors (see page 3 paragraph 1 where the vectors are resolutions), each with three values: likelihood, trend indicator, and impact indicator, where the output sets are mapped from the state history at the study place (see figure 2 where the values are related to their normalized counts).

35. As per claim 13, Goldenberg teaches the system of claim 1 as described above. Goldenberg further teaches the system wherein said rule system that governs the state transitions is the system with sets of logical rules, which evaluate both the logical and numerical functions to determine the system states (see page 2 paragraph 10 where the methodology encompasses a two-stage prediction system with both logical and numerical functions).

36. As per claim 14, Goldenberg teaches the system of claim 1 as described above. Goldenberg further teaches the system wherein said rule system that processes the structural components is a rule system with both logical and numerical functions mapping the structural components to supporting sets (see figure 2).

37. As per claim 15, Goldenberg teaches the system of claim 12, as understood, as described above. Goldenberg further teaches the system wherein said rule system that maps the state history to the output variables is a rule system with both logical and numerical functions mapping the state variables to the output variables which are described in Claim 12 (see figure 2 where the output variables are the prediction).

Claim Rejections - 35 USC § 103

38. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

39. **Claim 8** is rejected under 103(a) as being unpatentable over Goldenberg et al., "Early statistical detection of anthrax outbreaks by tracking over-the-counter medication sales" (see reference U on the attached PTO-892) in view of Armstrong et al., "Updated Guidelines for Evaluating Public Health Surveillance Systems" (see reference V on the attached PTO-892).

40. As per claim 8, Goldenberg teaches the apparatus of claim 7 as described above. Goldenberg does not explicitly teach the apparatus, as understood, wherein said set of state variables is healthy status, critical status, starting-unusual status, upward-trend-unusual status, peak-unusual status, downward-trend status, and ending-unusual status. Armstrong teaches the

apparatus, as understood, wherein said set of state variables is healthy status (see page 7, Measures paragraph 2 where the healthy status is years of healthy life) critical status (see page 7, Measures paragraph 1 where the critical status is the indices of severity), starting-unusual status (see page 7, Measures paragraph 3 where preventability includes the detectability), upward-trend-unusual status (see page 7, Measures paragraph 1 where the indices of frequency includes prevalence is used to show trends), peak-unusual status (see page 7, Measures paragraph 1 where the indices of frequency includes prevalence is used to show trend changes), downward-trend status (see page 7, Measures paragraph 1 where the indices of frequency includes prevalence is used to show trends), and ending-unusual status (see page 7, Measures paragraph 1 where the indices of frequency includes prevalence is used to show ending). It would be prima facie obvious to one of ordinary skill in the art at the time the invention was made to incorporate these features into Goldenberg. One of ordinary skill in the art would incorporate these features into Goldenberg to better ensure the integration of surveillance and health information systems (see Armstrong page 3, Summary paragraph 1).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neal R. Sereboff whose telephone number is (571) 270-1373. The examiner can normally be reached on Mon thru Thur from 7:30am to 5pm, with 1st Fri off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on (571) 272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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